

Marked-up copies of the foregoing amended claims are enclosed herewith.

REMARKS

The Official Action dated 18 June, 2002, has been carefully considered. In view of the foregoing amendments and these remarks, favourable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set in the June 18, 2002 Official Action. The initial due date for response, therefore, was September 18, 2002. A petition for a three (3) month extension of the response period is presented with this amendment and request for reconsideration, which is being filed within the three (3) month extension period.

The Official Action repeats and makes final the Restriction Requirement raised in the previous Official Action.

Furthermore, the previous rejection under 35 U.S.C. § 112, first paragraph, has been maintained. Consequently, claims 1-12, 16-17, 19 and 27-36 stand rejected as allegedly lacking adequate enablement.

Claims 4-7, 9, 27 and 30-32 stand rejected under 35 U.S.C. § 112 as allegedly being indefinite.

Claims 1-12, 16-17, 19 and 27-36 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not meeting the

written description requirement.

The above listed rejections constitute the entirety of the grounds set forth in the Official Action dated 18 June, 2002, for refusing allowance of this application. Each of these rejections is respectfully traversed for the reasons set forth below.

In accordance with the present amendments, the claims have been amended to specify a composition, rather than a cancer vaccine. Support for this amendment comes *inter alia* from the description at page 5, lines 16-27. The claims have been limited to fragments and derivatives of the amino acid sequence of Fig. 10, with claims to 791Tgp72 and methods for its isolation deleted. The terms "fragments" and "derivatives" have been further characterized. Support for this latter amendment comes *inter alia* from the claims as originally filed and from the description at page 14, lines 5-9. Accordingly, it is believed that the amendments to the claims introduce no new matter into the present specification. Entry of this amendment is, therefore, respectfully requested.

Turning attention to the Restriction Requirement, Applicants respectfully point out that the claims relating to Groups III and IV, as identified in the Official Action of October 2, 2001, have been deleted. This leaves only the question of whether it is proper to require restriction between Groups I and II.

Groups I and II, respectively, relate to the independent claims 1 and 13. Both of these claims were amended in response to the previous Official Action to call for fragments and derivatives of CD55 family polypeptides. They have been further amended presently to call for fragments and derivatives of the amino acid sequence of Fig. 10. The Examiner deems that restriction is appropriate on the basis that Durrant suggests the use of 791Tgp72 as an anti-cancer vaccine. While the correctness of this objection is not conceded, Applicant respectfully points out that claims 1 and 13 have the corresponding special technical feature of comprising, or encoding, fragments or derivatives of the amino acid sequence of 791Tgp72. Since the amino acid sequence of this antigen was unknown before the filing date of the instant application, such a special technical feature indeed defines a contribution over the prior art.

Applicants further respectfully refer the Examiner to the PCT Administrative instructions cited in the response to the previous Official Action. These clearly state that there is no lack of unity between a protein and the corresponding nucleic acid.

Reconsideration of the Restriction Requirement is therefore respectfully requested.

Turning attention now to the enablement rejection, Applicants respectfully point out that the claims have been amended to delete the term "cancer vaccine", and instead are directed to a "composition". Rejections based on the lack of

evidence that the claimed products lead to protection from cancer are therefore rendered moot.

Furthermore, the scope of the term "derivative" has been dramatically reduced to those having an amino acid sequence that differs from a fragment of Fig. 10 only by the substitution of 1 or 2 amino acids.

As pointed out in the response to the previous Official Action, the person skilled in the art would, at the priority and filing dates of the application, have been well able, without an undue need for experimentation, to identify fragments of the amino acid sequence of Fig. 10 that include a T cell epitope. Based on the knowledge of the characteristic residues of T cell epitopes, it would likewise be a matter of routine to make minor modifications to such fragments to arrive at the derivatives of the invention.

Indeed, the inventors have successfully applied algorithms that date from before the priority date of the application to the identification of T cell epitopes in the amino acid sequence of Fig. 10. Peptides based on the epitopes thus found are being produced for testing *in vivo* in mice.

Reconsideration and withdrawal of the enablement rejection is, therefore, respectfully requested.

In response to the rejection for alleged indefiniteness, the amino acid and nucleic acid sequences of Figs. 10 and 11 have been incorporated into the claims directly. This amendment therefore renders this ground of rejection moot.

As for the rejection based on alleged lack of written description, Applicants note that the Examiner's comments relate solely to the claimed derivatives. The present amendments now characterize such derivatives much more narrowly, as differing from fragments of the amino acid sequence only by the substitution of one or two amino acids. This is commensurate with the written description of the degree of identity between fragments of the amino acid sequence of Fig. 10 and the CDRs of the anti-idiotypic antibodies 105AD7 and 730, which appears at page 37, lines 16-28 of the present specification.

Applicants, therefore, respectfully request reconsideration and withdrawal of this rejection also.

Applicants believe that the present communication is fully responsive to the Official Action of June 18, 2002. In view of the foregoing amendments and remarks, it is respectfully submitted that all rejections have been overcome.

DANN DORFMAN HERRELL and  
SKILLMAN, P.C.

Attorneys for Applicant

By Patrick J. Hagan  
Patrick J. Hagan  
Registration No. 27,643

PJH:ksk

MARKED-UP VERSION OF AMENDED CLAIMS

1. (Twice amended) A [cancer vaccine] composition comprising a fragment of a polypeptide of the CD55 family or a derivative thereof, wherein said fragment or derivative contains a T cell epitope, and wherein [the vaccine is capable of inducing an immune response in a patient, said immune response being a T cell response] said fragment is of at least seven contiguous amino acids from the following amino acid sequence:

Met Thr Val Ala Arg Pro Ser Val Pro Ala Ala Leu Pro Leu Leu Gly  
1 5 10 15

Glu Leu Pro Arg Leu Leu Leu Leu Val Leu Leu Cys Leu Pro Ala Val  
20 25 30

Trp Gly Asp Cys Gly Leu Pro Pro Asp Val Pro Asn Ala Gln Pro Ala  
35 40 45

Leu Glu Gly Arg Thr Ser Phe Pro Glu Asp Thr Val Ile Thr Tyr Lys  
50 55 60

Cys Glu Glu Ser Phe Val Lys Ile Pro Gly Glu Lys Asp Ser Val Ile  
65 70 75 80

Cys Leu Lys Gly Ser Gln Trp Ser Asp Ile Glu Glu Phe Cys Asn Arg  
85 90 95

Ser Cys Glu Val Pro Thr Arg Leu Asn Ser Ala Ser Leu Lys Gln Pro  
100 105 110

Tyr Ile Thr Gln Asn Tyr Phe Pro Val Gly Thr Val Val Glu Tyr Glu  
115 120 125

Cys Arg Pro Gly Tyr Arg Arg Glu Pro Ser Leu Ser Pro Lys Leu Thr  
130 135 140

Cys Leu Gln Asn Leu Lys Trp Ser Thr Ala Val Glu Phe Cys Lys Lys  
145 150 155 160

Lys Ser Cys Pro Asn Pro Gly Glu Ile Arg Asn Gly Gln Ile Asp Val  
165 170 175

Pro Gly Gly Ile Leu Phe Gly Ala Thr Ile Ser Phe Ser Cys Asn Thr  
180 185 190

Gly Tyr Lys Leu Phe Gly Ser Thr Ser Ser Phe Cys Leu Ile Ser Gly  
195 200 205

Ser Ser Val Gln Trp Ser Asp Pro Leu Pro Glu Cys Arg Glu Ile Tyr  
210 215 220

Cys Pro Ala Pro Pro Gln Ile Asp Asn Gly Ile Ile Gln Gly Glu Arg  
225 230 235 240

Asp His Tyr Gly Tyr Arg Gln Ser Val Thr Tyr Ala Cys Asn Lys Gly  
245 250 255

Phe Thr Met Ile Gly Glu His Ser Ile Tyr Cys Thr Val Asn Asn Asp  
260 265 270

Glu Gly Glu Trp Ser Gly Pro Pro Pro Glu Cys Arg Gly Lys Ser Leu  
275 280 285

Thr Ser Lys Val Pro Pro Thr Val Gln Lys Pro Thr Thr Val Asn Val  
290 295 300

Pro Thr Thr Glu Val Ser Pro Thr Ser Gln Lys Thr Thr Thr Lys Thr  
305 310 315 320

Thr Thr Pro Asn Ala Gln Ala Thr Arg Ser Thr Pro Val Ser Arg Thr  
325 330 335

Thr Lys His Phe His Glu Thr Thr Pro Asn Lys Gly Ser Gly Thr Thr  
340 345 350

Ser Gly Thr Thr Arg Leu Leu Ser Gly His Thr Cys Phe Thr Leu Thr  
355 360 365

Gly Leu Leu Gly Thr Leu Val Thr Met Gly Leu Leu Thr  
370 375 380

or wherein said derivative varies from said fragment only by the  
substitution of 1 or 2 amino acids.

5. (Thrice amended) A [cancer vaccine] composition according to claim 1 wherein the fragment or derivative includes part or all of the amino acid sequence consisting of amino acids 97-159 of [Fig. 10] the sequence shown in claim 1.

6. (Thrice amended) A [cancer vaccine] composition according to claim 5 wherein the fragment or derivative includes a sequence having at least five amino acids identical with corresponding amino acids of a contiguous stretch of seven



amino acids contained within amino acids 121-128 or 151-158 of [Fig. 10] the sequence shown in claim 1.

7. (Thrice amended) A [cancer vaccine] composition according to claim 1 wherein the fragment or derivative includes a sequence having at least six amino acids identical with corresponding amino acids of a contiguous stretch of nine amino acids contained within amino acids 83-93 of [Fig. 10] the sequence shown in claim 1.
11. (Amended) A [cancer vaccine] composition according to claim [10] 1 wherein the fragment is of at least nine contiguous amino acids.
12. (Amended) A [cancer vaccine] composition according to claim 11 wherein the fragment is of at least 13 contiguous amino acids.
13. (Thrice amended) A [cancer vaccine] composition comprising a nucleic acid molecule which encodes a fragment or derivative as specified in claim 1 [, wherein the vaccine is capable of inducing an immune response in a patient, said immune response being a T cell response].
14. (Twice amended) A [cancer vaccine] composition according to claim 13 having part of [a] the nucleic acid sequence [as] shown [in Fig. 10] below:

ccgctgggag tagctggagc tgggagagat cgggagagag cgtccttatt ctaacccggc 60  
 gggcc atg acc gtc ggc cgg ccg agc gtg ccc ggc ggc ctg ccc etc etc 110  
 ggg gag ctg ccc cgg ctg ctg ctg ctg ctg ttg tgc ctg ccg gcc 158  
 gtg tgg ggt gac tgt ggc ctt ccc cca gat gta cct aat gcc cag cca 206  
 gct ttg gaa ggc cgt aca agt ttt ccc gag gat act gta ata acg tac 254  
 aaa tgt gaa gaa agc ttt gtg aaa att cct ggc gag aag gac tca gtg 302  
 atc tgc ctt aag ggc agt caa tgg tca gat att gaa gag ttc tgc aat 350  
 cgt agc tgc gag gtg cca aca agg cta aat tct gca tcc etc aaa cag 398  
 cct tat atc act cag aat tat ttt cca gtc ggt act gtt gtg gaa tat 446  
 gag tgc cgt cca ggt tac aga aga gaa cct tct cta tca cca aaa cta 494  
 act tgc ctt cag aat tta aaa tgg tcc aca gca gtc gaa ttt tgt aaa 542  
 aag aaa tca tgc cct aat ccg gga gaa ata cga aat ggt cag att gat 590  
 gta cca ggt ggc ata tta ttt ggt gca acc atc tcc ttc tca tgt aag 638  
 aca ggg tac aaa tta ttt ggc tgg act tct agt ttt tgt ctt att tca 686  
 ggc agc tct gtc cag tgg agt gac ccg ttg cca gag tgc aga gaa att 734  
 tat tgt cca gca cca cca caa att gac aat gga ata att caa ggg gaa 782  
 cgt gac cat tat gga tat aga cag tct gta acg tat gca tgt aat aaa 830  
 gga ttc acc atg att gga gag cac tct att tat tgt act gtg aat aat 878  
 gat gaa gga gag tgg agt ggc cca cca cct gaa tgc aga gga aaa tct 926  
 cta act tcc aag gtc cca cca aca gtt cag aaa cct acc aca gta aat 974  
 gtt cca act aca gaa gtc tca cca act tct cag aaa acc acc aca aaa 1022  
 acc acc aca cca aat gct caa gca aca cgg agt aca cct gtt tcc agg 1070  
 aca acc aag cat ttt cat gaa aca acc cca aat aaa gga agt gga acc 1118  
 act tca ggt act acc cgt ctt cta tct ggg cac acg tgt ttc acg ttg 1166  
 aca ggt ttg ctt ggg acg cta gta acc atg ggc ttg ctg act tag 1211  
 ccaagaaga gtaagaaga aaatacacac aagtatacag actgttccca gtttcttaga 1271  
 cttatctgca tattggataa aataaatgca attgtgctct tcatttagga tgctttcatt 1331  
 gtctttaaga tgttttagga atgtcaacag agcaaggaga aaaaaggcag tccgtgaatc 1391  
 acattcttag cacacctaca cctcttgaaa atagaacaaac ttgcagaatt gagagtgatt 1451  
 cctttcctaa aagtgttaaga aagcatagag atttgttctt atttagaatg gcatcacgag 1511  
 gaaaagagag gaaaagtgat tttttccac aagatctgta atgttatttc caattataaa 1571  
 ggaataaaa aatgaaaaac attatttggg tatcaaaagc aaataaaaac ccaattcagt 1631  
 ctcttctaag caaaattgct aaagagagat gaaccacatt ataaagtaat ctttggtgt 1691

aagcatttt catctttcct tccggttggc aaaatatatt aaaggtaaaa catgctggg 1751  
aaccaggggt gttgatggg ataagggagg aatatagaat gaaagactga atcttccttt 1811  
gttcacacaa tagagtttg aaaaagcctg tgaaggtgt cttctttgac ttaatgtctt 1871  
taaaagtatc cacagatact acaatattaa cataagaaaa gattatatat tattcttgaa 1931  
tccagatgtc catagtcaaa ttgttaaatc ttattctttt gtaatattta tttatattta 1991  
tttatgacag tgaacattct gattttacat gtaaaacaag aaaagttgaa gaagatatgt 2051  
gaagaaaaat gtatttttcc taaatagaaa taaatgatcc cattttttg t 2102

or [Fig. 11] the nucleic acid sequence shown below:

tttaaacggg cctctagac tccagccgcc gctgccatc ttgtcgtcgt cgtccttgta 60  
gtcgtgcatg tggatgggt ggtggtggtt aaccatggtg gcggccgcc actatgctg 120  
atatctgcag aattcgatgg gcctagctgc gactcggcg agtcccgcg gcgcgtcctt 180  
gttctaagcc ggcgcgcc atg acc gtc gcg cgg ccg agc gtg ccc gcg gcg 231  
ctg ccc gtc ctc ggg gag ctg ccc cgg ctg ctg ctg ctg gtg ctg ttg 279  
tgc ctg ccg gcc gtg tgg ggt gac tgt ggc ctt ccc cca gat gta cct 327  
aat gcc cag cca gct ttg gaa ggc cgt aca agt ttt ccc gag gat act 375  
gta ata acg tac aaa tgt gaa gaa agc ttt gtg aaa att cct ggc gag 423  
aag gac tca gtg atc tgc ctt aag ggc agt caa tgg tca gat att gaa 471  
gag ttc tgc aat cgt agc tgc gag gtg cca aca agg cta aat tct gca 519  
tcc ctc aaa cag cct tat atc act cag aat tat ttt cca gtc ggt act 567  
gtt gtg gaa tat gag tgc cgt cca ggt tac aga aga gaa cct tct cta 615  
tca cca aaa cta act tgc ctt cag aat tta aaa tgg tcc aca gca gtc 663  
gaa ttt tgt aaa aag aaa tca tgc cct aat ccg gga gaa ata cga aat 711  
ggt cag att gat gta cca ggt ggc ata tta ttt ggt gca acc atc tcc 759  
ttc tca tgt aac aca ggg tac aaa tta ttt ggc tcc act tct agt ttt 807  
tgt ctt att tca ggc agc tct gtc cag tgg agt gac ccg ttg cca gag 855  
tgc aga gaa att tat tgt cca gca cca cca caa att gac aat gga ata 903  
att caa ggg gaa cgt gac cat tat gga tat aga cag tct gta acg tat 951  
gca tgt aat aaa gga ttc acc atg att gga gag cac tct att tat tgt 999  
act gtg aat aat gat gaa gga gag tgg agt ggc cca cca cct gaa tgc 1047  
aga gga aaa tct cta act tcc aag gtc cca cca aca gtt cag aaa cct 1095

acc aca gta aat gtt cca act aca gaa gtc tca cca act tct caq aaa 1143  
acc acc aca aaa acc acc aca cca aat gct caa gca aca cgg act aca 1191  
cct gtt tcc acc aca acc aag cat ttt cat gaa aca acc cca aat aaa 1239  
gga agt gga acc act tca ggt act acc cgt ctt cta tct ggg cac acg 1287  
tgt ttc acc ttg aca ggt ttg ctt ggg acg cta gta acc atg ggc ttg 1335  
ctg act tag ccaaagaaga gtaagaaga aatcacac aagtatacag 1384  
actgttcta gtttcttaga cttatctga tattggataa aataaatga attgtctct 1444  
tcatttaga tgctttcatt gtctttaaga totgttagga atgtcaaca 1493

19. (Amended) A method of treating a patient having cancer, the method comprising administering to the - patient a therapeutically effective amount of a [cancer vaccine] composition as defined in claim 1.

34. (Amended) A [cancer vaccine] composition according to claim 1, wherein said T cell epitope is a T cell epitope of said polypeptide of the CD55 family.